

PSJ17 Exh 81

From: Kathleen.Meriwether@ey.com
To: Baldassano, Valli F.
CC: John.DoyleJr@ey.com; Trina.Scott@ey.com
Sent: 1/2/2008 8:26:57 PM
Subject: Happy New Year
Attachments: Cephalon - SOW 12-21-07DRAFT.doc.zip

Valli:

Hope you had some (well-earned) time off with your family over the holidays. I did; it was great - now have to reacclimate....

Trina and I were wondering whether you had a chance to look at our latest draft proposal (another copy is attached, for your convenience) and would like to chat later this week about timing, expectations, etc.

We are fairly flexible, so let me know what works for you as you try to keep all the balls in the air over there!

KM

Kathleen Meriwether
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Philadelphia, PA 19103

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December 21, 2007

Ms. Valli Baldassano
Executive Vice President, Chief Compliance Officer
Cephalon, Inc.
41 Moores Road
Frazer, PA 19355

Assessment of Sales, Marketing and Promotional Activities – Phase II

Dear Ms. Baldassano:

This letter, together with the Master Agreement for Performance of Professional Services (“Agreement”) entered into as of August 1, 2006 between Ernst & Young LLP and Cephalon, Inc., sets forth the terms and conditions on which Ernst & Young LLP (“Ernst & Young,” or “E&Y”) will perform certain professional services related to the above-referenced project for Cephalon, Inc. (the “Company”), as more fully described below (the “Services”).

The Services are advisory in nature. E&Y will perform the Services in accordance with applicable standards established by the American Institute of Certified Public Accountants (“AICPA”).

Services

Ernst & Young has been working with the Company’s internal audit group to review the strategies for launch and subsequent sales and promotional activities related to Fentora® as a means to assess the effectiveness of the compliance procedures the Company has implemented, as is reflected in a letter agreement dated July 20, 2007 (Phase I). In reviewing the focus areas identified, Ernst & Young was asked to assess 1) compliance with the Company’s compliance policies, procedures, and controls, and 2) identify whether any gaps exist in such policies, procedures, and internal controls based on our knowledge of industry leading practices, and 3) the process used by the Company to enforce and monitor such policies and procedures.

Certain procedures, as outlined below, were followed in Phase I in order to address each of the focus areas:

1. Discovery
 - Obtain and evaluate relevant documents and data associated with the identified focus areas as set forth below.
 - Conduct interviews of identified Company personnel with involvement in the focus areas.

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- Develop methodology to conduct analysis of information and activities (e.g., sample selection, review criteria).
2. Assessment
- Select the sample of activities/transactions/documents to be analyzed for each focus area.
 - Obtain and analyze supporting documentation for selected sample transactions/documents in each focus area.
 - Analyze documents, data, and information obtained during the interview process to identify vulnerabilities in processes and controls.
 - Attend and conduct “live” review of selected activities.
3. Observations and Recommendations
- Summarize observations and formulate recommendations for enhancing processes and controls.
 - Present observations and recommendations to the Company.

Subsequent to the presentation of the results of Phase I of the assessment to the Company, the Company asked Ernst & Young to conduct a supplemental review of certain areas identified for follow-up, as is more fully set forth below (Phase II of the Project):

Focus Area	Description	Estimated Fees
1. Internal marketing and tactical plans	As the recent Internal Audit report (Phase I) found that marketing and tactical plans were written in such a way that may give regulators the incorrect appearance that off-label promotion is occurring and being planned. Areas of focus: <ul style="list-style-type: none"> • Work with key marketing personnel to put into place a self monitoring plan. • Develop appropriate training materials on creation of documents and relevant regulatory/compliance considerations. 	\$10,000
2. Promotional and Regulatory Review of Materials	The current promotional and regulatory review process of materials does not have a "minimum standards" list with which to review items. Areas of focus: <ul style="list-style-type: none"> • Develop and implement formal written criteria for the review and 	\$15,000

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	approval of promotional materials by area, i.e., Medical, Legal, and Regulatory), and provide concrete delineation of areas of review/responsibility for each group.	
3. Fair Market Value Methodology	<p>No formal Fair Market Value (FMV) methodology has been adopted or utilized to control and benchmark fee-for-service arrangements with HCPs. Areas of Focus (in conjunction with internal and external personnel):</p> <ul style="list-style-type: none"> • Implement a formal FMV methodology. • Work with process owners in the implementation of the FMV process. • Assess all fee-for-service arrangements to ensure compliance with any newly adopted FMV methodology. 	\$25,000
4. Cephalon Speaker Programs (CSPs)	<p>No formal “live audits” are currently being conducted. A formal tracking process does not capture compliance exceptions or violations by a CSP speaker. Sales representatives do not sign any documentation that confirms a program took place and conformed to guidelines. Robust compliance/regulatory training is not conducted until a newly nominated speaker has been invited to a regional or national speaker training program. Areas of focus:</p> <ul style="list-style-type: none"> • Implement a CSP monitoring program. • Implement a process where by the sales representative and the CSP speaker attest to the completion of the program and that it conformed to Cephalon’s policies. • Implement a tracking mechanism 	\$10,000

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	to track and capture CSP speaker violations and provide for appropriate follow-up.	
5. <i>WLF</i> Papers	<p>The distribution of “WLF” articles is not monitored and tracked. Areas of focus:</p> <ul style="list-style-type: none"> • Implement a WLF tracking mechanism. • Monitor both eMIRF requests along with WLF requests. 	\$10,000
6. Sales Representatives Call Universe	<p>Call universes are not monitored for adherence to appropriate prescriber procedures. Focus area:</p> <p>Implement a monitoring plan to verify that target HCPs are appropriate prescribers.</p>	\$25,000
7. Cephalon Consultant Meeting Policy (CMP)	<p>Though the Cephalon Consultant Meeting Policy (CMP) has a requirement that a consultant meeting file be maintained and specific documents should be included post-meeting, we were not able to receive all our requested policy documents in a reasonable timeframe.</p> <p>Meeting summaries do not appear to be written in a consistent manner and the content often includes HCP personal comments regarding the venue or program.</p> <p>Focus Areas:</p> <ul style="list-style-type: none"> • Develop an SOP that establishes a central repository for all completed consultant meeting files • Create a guideline to guide the writing of consultant meeting executive summaries • Develop a monitoring plan to review consultant meeting files to ensure all appropriate documentation is retained. 	\$ 50,000
8. “Keystone” System	Scientific Communications “Keystone” system and the sales force’s SFA systems are not monitored to look for joint or	\$ 20,000

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	<p>“piggy back” sales calls. Focus Area:</p> <ul style="list-style-type: none">• Implement a monitoring plan Monitor the Keystone system and the SFA system to ensure appropriate call activity is taking place.	
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Timing

The work associated with this project will begin at a mutually agreed upon time. We anticipate the review of materials and additional interviews will be completed within eight to twelve weeks after commencement of this Phase II engagement and will require an estimated 300 to 400 hours, depending on availability of information and access to interviewees.

Work Product

The product of our Services will be, at the request of the Company, a Findings and Recommendations Report to the Company, which will outline the status of our Services and any findings and recommendations resulting from the performance of the Services. The actual form and timing of the Report we will deliver will be discussed with and agreed to with you.

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Fees and Expenses

Based on the focus areas defined above, it is estimated that our fees for all of the focus areas identified in this Phase II Project will be in the range of \$150,000 to \$180,000. Ernst & Young shall bill the Company monthly for Ernst & Young's fees and expenses in a summary fashion. In addition, the Company shall reimburse Ernst & Young for allocated and direct expenses incurred in connection with the performance of the Services as defined in the Agreement. Payment is due within 30 days of receipt of our invoice, and Ernst & Young may charge a late payment fee of 1½% per month on any unpaid balance due to Ernst & Young. All amounts due to Ernst & Young must be paid in full before Ernst & Young will issue its final Report.

We appreciate the opportunity to assist you with this project. Please indicate the Company's agreement with the terms hereof by executing it where indicated below and returning it to Kathleen Meriwether at the above address.

Very truly yours,

AGREED TO AND ACCEPTED BY:

CEPHALON, INC.

Name

Title

Date

Address: 41 Moores Road
Frazer, PA 19355

Telephone: 610.883.5794